

b.) Remarks

Claims 42, 44, 63, 64, 80 and 82 have been amended for better grammatical or idiomatic usage. No new matter has been added.

The previous rejection over Tsushima (U.S. Patent No. 6,036,974) and Roche (U.S. Patent No. 5,075,114) has been withdrawn. However, claims 42-53, 63-70 and 72-102 remain rejected under 35 U.S.C. §103(a) as being obvious over Morimoto (EP 0 650 826) in view of Tsushima and Roche, which was not specifically addressed in the April 7, 2008 Amendment. The undersigned apologies for any inconvenience that was inadvertently caused.

The Examiner's bases of rejection are set forth from pages 2-3 of the Office Action. According to the Examiner, Morimoto teaches compressing a tablet using a punch and die with spray lubricant, but does not teach tableting granules or use of stearic acid lubricants. Tsushima shows coating tablet surfaces with stearic acid and Roche shows polymer-coated granules.

This rejection is respectfully traversed.

This rejection was thought to be addressed previously when Applicants pointed out that Tsushima relates to a disparate process of producing an aqueous molding tablet by compressing wet material in a mold, removing a wet tablet from the mold after compression and drying the tablet. Moreover, Tsushima applies lubricant directly to the paste surfaces, not to the punch and die. Additionally, Applicants explained why Tsushima cannot be combined with Roche anyway. For all these reasons, it was

respectfully thought that the rejection was addressed, since Morimoto does not remedy these failings.

However, it is further seen from the following that any *prima facie* case of obviousness is, in any event, rebutted by the showings of unexpected improvements over the prior art. That is, the data of record illustrates conclusively that, when stearic acid is included in the molding material as in the prior art, only tablets with inferior hardness are obtained when the molding material is compressed at Applicants' tableting pressure of 0.7 to 1.3 ton/cm². This data is summarized and explained below to complete the record.

Table I shows the composition of the tablets produced in the experiments 3 and 4, and comparisons 4 and 5.

Table I

	experiment 3	experiment 4	comparison 4	comparison 5
granule	1000g (ref 1)	500g (ref 2)	1000g (ref 1)	1000g (ref 2)
lactose	700g	350g	700g	700g
crystalline cellulose	300g	150g	280g	280g
magnesium stearate				
(mixed with molding material)	0g	0g	20g (1.0% by weight)	20g (1.0% by weight)
magnesium stearate				
(provided on the tablet surface)	0.07 % by weight	0.03 % by weight	0g	0g

The salient difference between these is simply that experiments 3 and 4 (according to the present invention) have magnesium stearate on the tablet surface and comparisons 4 and 5 have it within the tablet (according to the prior art).

Table II shows the hardness of tablets obtained at various tableting pressures. As shown below, tablets of the present invention in experiments 3 and 4 are at least 25% harder than the prior art when tableted at low pressure.

Table II

tableting pressure (ton/cm ²)		tablet hardness		
	experiment 3	experiment 4	comparison 4	comparison 5
1.3	5.0	5.5	2.0	2.0
2.6	10.0	11.0	4.5	5.0
3.9	14.0	15.0	9.0	9.5

In view of the above amendments and remarks, Applicants submit that all of the Examiner's concerns are now overcome and the claims are now in allowable condition.

Accordingly, reconsideration and allowance of this application is earnestly solicited.

Claims 42-53, 63-70 and 72-102 remain presented for continued prosecution.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,

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